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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,430	09/26/2006	Koki Nakamura	1012777-000065	2931

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

NOTIFICATION DATE	DELIVERY MODE
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05/19/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/594,430	Applicant(s) NAKAMURA, KOKI	
	Examiner Paul A. Zucker	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/30/09, 2/13/08, 9/26/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-14, and election of the species NBD-4, claims 1-7 readable thereon, in the reply filed on 16 February 2010 is acknowledged. Claims 8-28 are held withdrawn from consideration as being drawn to non-elected invention.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on application JP 2004-096080 filed in Japan on 29 March 2004. No copy of this application is present in the application file. As the other two priority documents were transmitted by the International Authority, clarification is requested.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 does not appear to represent a real chemical species but rather an abstract idea of a repeating unit since it contains no terminal focal point moiety. Clarification and amendment are required. Claim 1 and its dependants are therefore rendered indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the dithioacetals of thiomethylbenzaldehyde, -hydroxybenzaldehyde, and a monothioquinone -substituted acetaldehyde and it does not reasonably provide enablement for any other linker group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

These factors include, but are not limited to:

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- a. the breadth of the claims: In the instant case the claims are exceptionally broad since the linkers X, L1 and L2 may be, without limitation, any divalent group and can range, for example, from a covalent bond to a steroid to a protein to a molecule of DNA, producing an infinite number of possibilities.
- b. the nature of the invention: The instantly claimed invention involves the synthesis of high density molecules which, as the generations of branching progress, become increasingly more densely packed (Grayson et al, Chemical Reviews, 2001,101, page 3822, paragraph bridging columns 1 and 2) resulting in failure to properly couple due to increasing steric hindrance. Grayson further discusses (Page 3822, column 1, first full paragraph) synthetic difficulties that arise from failure in coupling such as difficulty in removing products of incomplete reaction and side products. In the present case, an additional complicating factor is that formation of the linkage between generations is a reversible process and requires that the last-formed linkage not undergo the reverse reaction under coupling conditions for formation of the next generation. Thus the instantly claimed compounds must simultaneously satisfy a variety of steric and chemical criteria which will inherently limit the nature of the linkers that can be used. One of ordinary skill in the art could not predict how such factors could be expected to balance for the diverse array of linkers instantly claimed.
- c. the state of the prior art: the state of the prior art would not allow one to predict in advance, based on Applicants' disclosure which of the variety of

possible reaction conditions and isolation/purification techniques, or combinations thereof, could be used to successfully produce dendron/dendrimer from any other linker group. With regard to the level of predictability in the art: Chemistry is unpredictable. See *In Re Marzocchi and Horton* 169 USPQ at 367 paragraph 3. As stated in the preface to a recent treatise:

“Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work.....Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious).....” Dorwald F. A. *Side Reactions in Organic Synthesis*, 2005, Wiley: VCH, Weinheim pg. IX of Preface.

As a further example of the difficulties encountered in synthesis, see the present specification at page 35, lines 13-17;

- e. the amount of direction provided by the inventor: The inventor provide direction for the production of dendrons and dendrimers based on the dithioacetals of dithioacetals of thiomethylbenzaldehyde, hydroxybenzaldehyde, and a monothioquinone-substituted acetaldehyde. No direction is provided for the selection of any other linkers having substantially different structures.
- f. the existence of working examples: The only working examples provided are directed to the production of compounds 1-11 as set forth in the examples in the specification which employ the linkers set forth above.

Thus given the infinite number of possible linker structures, the severe steric constraints, linker reactivity, the difficulties inherent in the synthetic endeavor and guidance for linker selection provided by Applicant, the Examiner concludes that undue experimentation is required to make the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 6. Claims 1 and 4-7 rejected under 35 U.S.C. 102(b) as being anticipated by Malenfant (Chemical Materials, Dendrimer-Supported Oligothiophene Synthesis: Aliphatic Ether Dendrimers in the Preparation of Oligothiophenes with Minimal Substitution, 1999, 11 pages 3420-3422). Malenfant discloses (Page 3421, Scheme I) the

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compounds **1-3** and **5** which correspond to dendrons as instantly claimed in which L_1 , $X = -CH_2O-$ and $L_2 =$ a bond, and has generation number equal to 3. The Examiner considers the surface to be covered with phenyl-protected hydroxyl groups. Malenfant therefore anticipates claims 1 and 4-7.

7. Claims 1-5 rejected under 35 U.S.C. 102(b) as being anticipated by Ranu et al (Synlett, 2002, 5, pages 727-730). Ranu discloses (Page 728, Table, product entries 10-12) compounds **1-3** and **5** which correspond to dendrons as instantly claimed in which $L_1 = -O\text{-phenylene-}$, $X = S$ and $L_2 =$ a bond with generation number equal to 1. Malenfant therefore anticipates claims 1-5.

Conclusion

8. Claims 1-28 are pending. Claims 1-7 are rejected. Claims 8-28 are held withdrawn from consideration as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/
Primary Examiner, Art Unit 1621